Ex 17 - MCKMDL00355349-5415

Plaintiffs' Opposition to Defendants' Motion for Summary Judgment on Proximate Causation Grounds

negotiation of this Agreement, and is taking no action by entering into this Agreement, that can be interpreted to be directly or indirectly endorsing or approving the system that McKesson is currently utilizing to meet its obligations under the CSA and the implementing regulations. Going forward, DEA's actions in fulfilling the oversight of McKesson under this Agreement, including the receipt of information and/or its participation in meetings with McKesson representatives, shall not be construed or interpreted to be directly or indirectly endorsing or approving the system that McKesson is utilizing to meet its obligations under the CSA and the implementing regulations.

- DEA agrees to accept at DEA Headquarters the information regarding suspicious orders as described in subsection II.1.c. of this Agreement.
- c. In the event that DEA discovers information about conduct during the Covered Time Period that may warrant administrative action, and which is not otherwise included under the Covered Conduct, DEA shall favorably consider McKesson's entry into this Agreement, the Compliance Addendum, and the civil penalties paid pursuant to the Settlement Agreement and Release; all actions taken by McKesson pursuant to this Agreement and Compliance Addendum; any remedial actions taken by McKesson to address the alleged or perceived violative conduct; and the compliance history of McKesson at the particular facility, and at other McKesson facilities.
- d. Unless DEA determines that McKesson is in noncompliance with the terms of this Agreement, after providing McKesson with prior written notice of alleged noncompliance with the terms of this Agreement and providing McKesson with at least thirty (30) days to respond to any such notice, DEA agrees that it will lift the suspension of McKesson Aurora's distribution center, DEA Certificate of Registration PM0018425, and, if needed, grant any requisite registration renewal, no later than the end of the Aurora Suspension Period.
- e. Unless DEA determines that McKesson is in noncompliance with the terms of this Agreement, after providing McKesson with prior written notice of alleged noncompliance with the terms of this Agreement and providing McKesson with at least thirty (30) days to respond to any such notice, DEA agrees that it will lift the suspension of McKesson Livonia distribution center, DEA Certificate of Registration PM0030849, and, if needed, grant any requisite registration renewal, no later than the end of the Livonia Suspension Period.
- f. Unless DEA determines that McKesson is in noncompliance with the terms of this Agreement, after providing McKesson with prior written notice of alleged noncompliance with the terms of this Agreement and providing McKesson with at least thirty (30) days to respond to any such notice, DEA agrees that it will lift the suspension of McKesson WCH distribution center, DEA Certificate of Registration RM0220688, and, if needed, grant any requisite registration renewal, no later than the end of the WCH Suspension Period.

- g. Unless DEA determines that McKesson is in noncompliance with the terms of this Agreement, after providing McKesson with prior written notice of alleged noncompliance with the terms of this Agreement and providing McKesson with at least thirty (30) days to respond to any such notice, DEA agrees that it will reinstate the ability of the McKesson Lakeland distribution center, DEA Certificate of Registration PM0000771, to distribute the controlled substances containing the drug code for Schedule II hydromorphone products, that is, DEA drug code 9150, no later than the end of the Lakeland Suspension Period.
- 3. Release by DEA. In consideration of the fulfillment of the obligations of McKesson under this Agreement, DEA agrees to:
 - a. Fully and finally release McKesson, together with its subsidiary entities, distribution facilities, and registrants, along with its officers, directors, employees, successors, and assigns (collectively, the "Released Parties") from any and all administrative claims within DEA's enforcement authority under 21 U.S.C. §§ 823 & 824 related to the Covered Conduct; and
 - b. Refrain from filing or taking any administrative actions against the Released Parties within DEA's enforcement authority under 21 U.S.C. §§ 823 & 824, based on the Covered Conduct only to extent that such conduct was or could have been discovered by DEA through the exercise of due diligence through the examination of open investigations and inspections in existence as of the Effective Date of this Agreement, and the review of the reports and records McKesson submitted to DEA prior to the Effective Date of this Agreement. This release applies only to administrative actions brought before or by DEA.

Notwithstanding the releases by DEA contained in this Paragraph, DEA reserves the right to seek to admit evidence of the Covered Conduct for proper evidentiary purposes in any other administrative proceeding against the Released Parties for non-Covered Conduct. Further, nothing in this Paragraph shall prohibit or limit any other agency within the Department of Justice, any State attorney general, or any other law enforcement, administrative, or regulatory agency of the United States or any State thereof, from initiating administrative, civil, or criminal proceedings with respect to the Covered Conduct. DEA shall, as obligated in fulfilling its statutory duties, assist and cooperate with any agency that initiates an investigation, action, or proceeding involving the Covered Conduct. At McKesson's request, DEA agrees to disclose the terms of this Agreement to any other agency and will represent, assuming McKesson is in compliance with this Agreement, that the allegations raised by DEA, as defined in the Covered Conduct, have been adequately addressed. This release is applicable only to the Released Parties and is not applicable in any manner to any other individual, partnership, corporation, or entity.

4. Release by McKesson. McKesson fully and finally releases the United States of America, its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) which McKesson has asserted, could have asserted, or may assert in the future against the United States of America, its

agencies, employees, servants, and agents, related to the Covered Conduct and the United States' investigation and prosecution thereof.

- 5. Reservation of Claims. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including McKesson) are the following:
 - a. Any potential criminal liability;
 - b. Any civil, criminal or administrative liability arising under Title 26, U.S. Code (Internal Revenue Code);
 - Any administrative liability to the United States other than administrative claims released in Paragraph II.3.a. and b.
 - d. Any civil liability to the United States, other than the civil claims released in the 2017 Settlement Agreement and Release; or
 - e. Any liability based upon any obligation created by or arising under this Agreement.

III. Miscellaneous

- Binding on Successors. This Agreement is binding on McKesson, and its respective successors, heirs, transferees, and assigns.
- Costs. Each Party to this Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.
- 3. No Additional Releases. This Agreement is intended to be for the benefit of the Parties and the Released Parties only, and by this instrument the Parties do not release any claims against any other person or entity other than the Released Parties.
- 4. <u>Effect of Agreement</u>. This Agreement constitutes the complete agreement between the Parties. All material representations, understandings, and promises of the Parties are contained in this Agreement, and each of the parties expressly agrees and acknowledges that, other than those statements expressly set forth in this Agreement, it is not relying on any statement, whether oral or written, of any person or entity with respect to its entry into this Agreement or to the consummation of the transactions contemplated by this Agreement. Any modifications to this Agreement shall be set forth in writing and signed by all Parties. McKesson represents that this Agreement is entered into with advice of counsel and knowledge of the events described herein. McKesson further represents that this Agreement is voluntarily entered into in order to avoid litigation, without any degree of duress or compulsion.

- 5. Execution of Agreement. This Agreement shall become effective (i.e., final and binding) on the date of signing by the last signatory (the "Effective Date"). The government agrees to notify McKesson immediately when the final signatory has executed this Agreement.
- 6. <u>Notices</u>. All communications and notices pursuant to this Agreement shall be made in writing to the following individuals, which notice information may be altered from time to time by either Party by written notification:
 - a. For DEA or DOJ:

Drug Enforcement Administration, Diversion Control Division, 8701 Morrissette Drive, Springfield, Virginia 22152;

Drug Enforcement Administration, Office of Chief Counsel, Diversion and Regulatory Litigation Section, 8701 Morrissette Drive, Springfield, Virginia 22152; and

U.S. Department of Justice, Criminal Division, Narcotic and Dangerous Drug Section, 145 N St. NE (2 Constitution Square), 2nd Floor, East Wing, Washington, D.C. 20530

b. For McKesson:

Senior Vice President, US Pharmaceutical, Regulatory Affairs and Compliance McKesson Corporation
One Post Street, 36th Floor
San Francisco, CA 94104

with copies to:

Vice President, U.S. Pharmaceutical, Regulatory Affairs & Compliance
McKesson Corporation
6535 State Highway 161
Irving, TX 75039-2402

Assistant General Counsel, US Pharmaceutical McKesson Corporation One Post Street, 36th Floor San Francisco, CA 94104

- Disclosure. McKesson and DEA may each disclose the existence of this Agreement and information about this Agreement to the public except for information designated as confidential.
- 8. <u>Confidentiality and Designation of Information.</u> McKesson and DEA agree that all transaction reports submitted to DEA contain information this is commercial or financial and privileged or confidential, and therefore exempt from disclosure under the Freedom of

Information Act ("FOIA"), 5 U.S.C. § 552. Such information may be exempt from disclosure under the Freedom of Information Act and any other state or federal law or regulation protecting such information from public disclosure and, upon receipt of a request to release such, DEA agrees to provide McKesson reasonable opportunity to respond to any such requests.

- 9. Execution in Counterparts. This Agreement may be executed in counterparts, each of which constitutes an original, and all of which shall constitute one and the same agreement. Copies or facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.
- 10. <u>Authorizations</u>. The individuals signing this Agreement on behalf of McKesson represent and warrant that they are authorized by McKesson to execute this Agreement. The individuals signing this Agreement on behalf of DEA represent and warrant that they are signing this Agreement in their official capacities and that they are authorized by DEA to execute this Agreement.
- 11. Choice of Law and Venue. This Settlement Agreement and Release shall be construed in accordance with the laws of the United States, and either Party may seek judicial enforcement of this Agreement upon a material breach by the other Party. The Parties agree that the jurisdiction and venue for any dispute arising between and among the Parties to this Agreement shall be any federal court of competent jurisdiction. This provision, however, shall not be construed as a waiver of the jurisdictional provisions of the CSA, as amended.

[Signature page to follow]

IN WITNESS WHEREOF, the Parties hereto have duly executed this Administrative Memorandum of Agreement.

On Behalf of McKesson Corporation:

Mark Walchirk President, US Pharmaceutical

McKesson Corporation

Dated: 1-5-17

On Behalf of the United States Department

of Justice, Drug Enforcement Administration:

Chuck Rosenberg

Acting Administrator

Drug Enforcement Administration

Dated

Assistant Administrator, Diversion Control

Division

Drug Enforcement Administration

Dated: 1-17-17

APPENDIX A

Appendix A McKesson US Pharma DCs Confidential Business Information - FOIA Exempt

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8130	ANCHORAGE	5491 Electron Dr Suite A	Anchorage	AK	99518-1072	RM0227430
8148	ATLANTA	2975 Evergreen Drive	Duluth	GA	30096-5888	PR0040357
8126	BIRMINGHAM	6775 Jefferson Metro Pkwy	McCalla	AL	35111-3955	RM0336950
8110	BOSTON	9 Aegean Dr	Methuen	MA	01844-1596	PM0020850
8113	BUFFALO	2700 N. America Dr.	West Seneca	NY	14224-5318	PM0003094
8144	CHICAGOLAND	1995 McKesson Street Suite 101	Aurora	IL	60502-7703	RM0380484
8145	CLEAR LAKE	2101 12th Ave S.	Clear Lake	1A	50428-0000	RM0490590
8005	CONCORD Packaging	7101 Weddington Road	Concord	NC	28027	RM0306541
8115	CONROE	3301 Pollok Drive	Conroe	TX	77303	RM0328408
8176	DELRAN	400 Delran Pkwy	Delran	NI	08075-1248	RM0173055
8131	DENVER	14500 E. 39th Ave	Aurora	CO	80011-1210	PM0018425
8128	EVERETT	710 - 132nd St. S.W.	Everett	WA	98204-7322	PM0150538
8138	HONOLULU	80 Sand Island Access Rd	Honolulu	HI	96819-4904	PM0001014
8175	LaCROSSE	3003 Airport Road	LaCrosse	WI	54603-1258	RM0220537
8195	LAKELAND	1515 Kendrick Lane	Lakeland	FL	33805-2501	PM0000771
8132	LIVONIA	38220 Plymouth Rd	Livonia	MI	48150-1050	PM0030849
8149	MEMPHIS	4836 Southridge Blvd	Memphis	TN	38141-8300	PM0001951
8772	NEW CASTLE	2798 New Butler Rd	New Castle	PA	16101-3229	RM0258601
8106	NRDC	8313 Polk Lane	Olive Branch	MS	38654	RM0421557
8165	OKLAHOMA CITY	4012 South Purdue	Oklahoma City	OK	73179-7816	RM0138328
8170	PHOENIX	495 S. 107th Ave	Tolleson	AZ	85353-9402	PM0021131
8173	PORTLAND	9700 SW Commerce Circle	Wilsonville	OR	97070-9688	PM0022929
8191	ROCKY HILL	280 Dividend Road	Rocky Hill	CT	06067-3782	PR0104S93
8182	SACRAMENTO	3775 Seaport Blvd	W.Sacramento	CA	95691-3472	PM0021535
8180	SALT LAKE CITY	1900 South 4490 West	Salt Lake City	UT	84104-4720	PM0023046
8147	SoCAL	9501 S. Norwalk Blvd.	Santa Fe Springs	CA	90670-2929	PF0000012
8183	St. LOUIS	1 Commerce Dr	O'Fallon	MO	63366-4413	PM0037374
8107	Stategic Redistribution Ctr	3400 Fraser St	Aurora	CO	80011-1219	RM035495B
8155	TRI STATES	1 John Henry Dr	Robbinsville	NJ	08691	RM0456411
8120	VIRGINIA	10504 McKesson Drive	Ruther Glen	VA	22546	RM0424363
8164	Wash.Ct. Hse.	3000 Kenskill Ave	Washington Ct. Hse.	OH	43160-8616	RM0220688

APPENDIX B

SETTLEMENT AND RELEASE AGREEMENT AND ADMINISTRATIVE MEMORANDUM OF AGREEMENT

This Settlement and Release Agreement and Administrative Memorandum of Agreement ("Agreement") is entered into on this 2 day of May 2008, by and between the United States Department of Justice, Drug Enforcement Administration (hereinafter "DEA") and McKesson Corporation including facilities doing business as McKesson Pharmaceutical and McKesson Drug Company (hereinafter "McKesson") (each a "Party" and collectively the "Parties").

APPLICABILITY

This Agreement shall be applicable to McKesson and all McKesson DEA registered facilities as identified in Appendix A.

BACKGROUND

WHEREAS, on August 4, 2006, DEA, by its Deputy Assistant Administrator, Joseph T. Rannazzisi, issued an Order to Show Cause ("Order #1") to McKesson, with respect to its Lakeland distribution center located at 1515 West Bella Vista Street, Lakeland, Florida 33805 (the "Lakeland Facility"); and

WHEREAS, Order #1 alleged, among other things, that McKesson failed to maintain effective controls at the Lakeland Facility against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain customers of McKesson; and

WHEREAS, after service of Order #1 on McKesson, representatives of DEA and McKesson entered into discussions on how best to resolve the issues raised in the Order; and

WHEREAS, on November 1, 2007, DEA, by its Deputy Assistant Administrator, Joseph T. Rannazzisi, issued a second Order to Show Cause to McKesson ("Order #2," and "Orders" when jointly referring to Order #1 and Order #2), with respect to its Landover distribution center located at 7721 Polk Street, Landover, Maryland, 20785 (the "Landover Facility"); and

WHEREAS, Order #2 alleged, among other things, that McKesson failed to maintain effective controls at the Landover Facility against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain customers of McKesson; and

WHEREAS, DEA alleges that McKesson failed to maintain effective controls at its Conroe, Texas distribution center (the "Conroe Facility") against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain customers of McKesson; and